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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,105

04/16/2004

Mark D. Soll

MER 04-024

9262

7590 10/02/2009
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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

10/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,105	Applicant(s) SOLL ET AL.	
	Examiner NEIL LEVY	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29,33,35-40 is/are pending in the application.
- 4a) Of the above claim(s) 35 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29,33, & 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 26-29,33,35 and 37-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/28/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 35,38-40 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention & species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/28/08

Claim Rejections - 35 USC § 112

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

“and the like” is indefinite

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for A premix of formula II and i, ii, iii, and v, does not reasonably provide enablement for an organic solvent, except for propylene glycol.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The solvents are typically used dermally, and as a premix, there is no

disclosure as to how much to use; examples are free of these solvents. An excess of solvent would be potentially toxic; perhaps that's why there is no guidance as to how to use this either as a feed supplement or premix.

Claim Rejections - 35 USC § 103

Claims 26-29, 33 % 37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over ALIG 6518296 in view of CLEVERLY et al US 2004/0037869 and HUBER 6569886 and FREEHAUF-US 20050136087

ALIG shows the instant compound at Table 1, A, Table I provides for haloalkyl as -example 4, as the fipronil substituted thioamide derivative. Compositions of the instant claimed formulation include components of paraffin, oils, and organic solvents, including glycols, like the instant organic of claim 33 (column 14, lines 33-41), with corn cobs and corn meals (column 14, lines 55) & surfactants (lines 55-59).

Additional parasitocides include avermectins (column 1, lines 17,18,35,45) & IGRs (lines 46,58, 66). Oral formulations for cattle, pets and other animals are at column 18, lines 12-16,25-28. Alig does not have all claimed components, as applicant points out.

CLEVERLY also provides fipronil derivatives [0088] and shows fipronil and avermectin [0062, 0065] of the instant formulations inclusive of a 20-60% [0043] corn cob or corn meal [0021] filler, pH modifier, 0.05-1% antioxidant [0049] and surfactant [0054-0060].

Tablet forms include 0.01-20% waxes (claim 53) [0189].

HUBER has fipronil derivatives, fed with ivermectins, & uses solvents in tablets, pills, and dietary supplements and premixes for medicated diets. carriers include waxes.

FREEHAUF has Avermectins as premix[0002,0052]. The instant claimed excipients are shown for a premix at [0016-0023] . These are the ingredients of instant claim 26, & 33 except for the solvent. The instant claim 26 is better shown for the premix components at [0025-0032]. It is not critical as to the specific pesticides one would use, so long as they are orally effective. Avermectin is one of the instantly claimed pesticides, so appropriate to the inclusion of the components as presented in the % presented for Avermectin by FREEHAUF.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use any of art recognized means, as of the ALIG formulations, modified as desired to permit application in feeds for animals. FREEHAUF details the excipients one would use for oral delivery as a pesticidal medicament as a tablet or feed premix.. It would be obvious to vary the form of the formulations to optimize the effect desired, depending upon the particular species and application method of interest, reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects. Applicant has not provided any objective evidence of nonobvious or unexpected results that the administration of the particular ingredients' combination or formulation provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability.

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Double Patenting

Claim 26-29, 33 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 4, 5, 8-10, 13, 15-21, 23-29, 33 of copending Application No. 11/580,731. Although the conflicting claims are not identical, they are not patentably distinct from each other because the 11/580,731 would anticipate the instant claimed invention. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

At this time, neither case has been allowed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/
Primary Examiner, Art Unit 1615
9/29/09